AUG 1 4 2000

K001604

510(k) Summary for DANA Diabecare®

1. SPONSOR

Sooil Development Co., Ltd.
111-1, Heukseokl-dong, Dongjak-ku
Seoul, 156-071
KOREA

Contact Person: Soo Bong Choi
Telephone: 82-441-845-2129 (Telephone)
82-441-845-2128 (Facsimile)

Date Prepared: May 23, 2000

2. DEVICE NAME

Proprietary Name: DANA Diabecare®
Common/Usual Name: Insulin infusion pump
Classification Name: Infusion pump

3. PREDICATE DEVICES

MiniMed® 507 insulin pump (MiniMed Technologies, K960001)

4. DEVICE DESCRIPTION

The DANA Diabecare® pump is a digitally controlled syringe pump that provides precise insulin delivery and monitoring of device functions. The DANA Diabecare® has two insulin delivery modes, the basal infusion rate and meal bolus injections. The user can program up to 12 basal infusion dosages in two-hour increments and three meal bolus injections daily. The basal infusion rate can be temporarily reduced to accommodate changes in activity levels, such as during exercise. The pump is battery-powered, water-resistant, very compact, and weighs only 60 grams.

The DANA Diabecare® pump is intended to be used with a proprietary insulin reservoir and the SUPERLINE infusion set. The insulin reservoir is a 3 ml plastic

syringe with a 300-unit insulin capacity. The SUPERLINE infusion set consists of a 5.50 cm length of tubing with a Luer-lock connector on the proximal end for attachment to the insulin syringe and a 27 G needle on the distal end. Two needle configurations are available, either a straight or a 90° needle (90° orientation of needle with respect to the tubing). The 90° needle is 6.5 mm long and is surrounded by a circular needle-fixing guide and wing for holding the needle in place. The straight needle is available in 15 and 19 mm lengths.

Additional accessories necessary for operation and maintenance of the pump, syringe, and infusion set are provided with the DANA Diabecare® pump.

5. INTENDED USE

The DANA Diabecare® is an external programmable syringe infusion pump used for the subcutaneous delivery of insulin for the treatment of diabetes mellitus. The pump is not intended for use with blood or blood products.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the proposed and predicate devices are external programmable pumps intended for the delivery of insulin for the treatment of diabetes mellitus. Neither the DANA Diabecare® or the MiniMed device are intended for the delivery of blood or blood products.

The proposed DANA Diabecare® and predicate MiniMed® 507 pumps are both compact, lightweight devices. The proposed device is somewhat smaller and much lighter than the predicate MiniMed pump.

The pump cases of both devices house a syringe reservoir, computer control unit, pump motor, and battery power source. One face of the proposed and predicate pump cases contains an LCD screen and a keypad for communication with the microprocessor.

The insulin reservoir for the proposed and predicate pumps is a 3-ml syringe with a 300 U capacity. In both devices, insulin is delivered to the patient through an infusion set.

The proposed DANA Diabecare® has two insulin delivery modes, a basal infusion rate and a meal bolus injection. The substantially equivalent pump has a square wave bolus mode in addition to the basal infusion and meal bolus modes that permits

the user to extend the bolus injection over a defined period of time. Both the DANA Diabecare® and MiniMed devices permit temporary suspension of the basal infusion. The accuracy of insulin delivery is identical for the two devices.

The DANA Diabecare® and the MiniMed® 507 pumps incorporate a number of important safety features to ensure the safe operation of the device. Both devices have safety checks incorporated into the system software to verify that the pump is functioning properly. If a malfunction is detected, the pump is automatically shut down and an alarm is sounded. Audible signals are also sounded when certain functions are completed.

7. PERFORMANCE TESTING

Test data was provided to demonstrate that the DANA Diabecare® is in compliance with the following safety and performance standards:

- EN 60601-1, "Medical electrical equipment – Part 1: General requirements for safety"
- EN 60601-1-2, "Collateral standard: Electromagnetic compatibility: Requirements and tests"
- EN 60601-2-24, "Medical electrical equipment – Part 2: Particular requirements for the safety of infusion pumps and controllers"

Additional performance testing was provided to demonstrate that:

- The pump functions at the operational temperature extremes of –20 to 40°C
- Insulin is stable, and retains potency, after at least five days of contact with the syringe and infusion set
- The motor can complete 41,490,000 revolutions without mechanical failure (equivalent to over 6 years of use at a daily insulin requirement of 50 units)

The insulin syringe reservoir and SUPERLINE infusion set (the only DANA Diabecare® components in contact with the fluid path) meet the requirements of ISO-10993 and General Program Memorandum G95-1, [Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"], (May 1, 1995) for external communicating devices in prolonged (24 hours to 30 days) indirect contact with blood. The SUPERLINE Infusion set and

syringe were demonstrated to be non-pyrogenic using the Limulus Amebocyte Lysate (LAL) Assay and In Vivo Rabbit Pyrogen Test.

Data was also included to support a three-year shelf life for the syringe and infusion set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2000

Ms. Cynthia J.M. Nolte
Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K001604
Trade Name: Dana Diabecare
Regulatory Class: LGZ
Product Code: II
Dated: May 23, 2000
Received: May 24, 2000

Dear Ms. Nolte:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Contol
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: DANA Diabecare®

Indications For Use:

The DANA Diabecare® is an external programmable syringe infusion pump used for the subcutaneous delivery of insulin for the treatment of diabetes mellitus. The pump is not intended for use with blood or blood products.

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cusenza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001604

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)